Gamma Cardio Soft

Gamma Cardio CG
ECG Multifunctional System

User Manual

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Introduction

Gamma Cardio CG is an Electrocardiographic diagnostic system (ECG) that records the standard 12 lead ECG one lead at time.

The system offers the high recording quality, the performance and the features included in high-end products with a straightforward user interface.

The Gamma Cardio CG system includes an acquisition unit that is connected to a personal computer through the USB port and a software ECG application for Windows systems.

The system is easily managed also by users without a specific computer skill.

Experienced users will quickly use this medical instrument thanks to graphic interface that resembles most commonly used Ecgs. Non-experienced users will easily record ECGs through the wizard that shows the recording procedure step by step.

Physicians have specific tools to simplify reporting. An interpretation assistant is also included to produce interpretation reports easily. In addition, the telemedicine functions and the electronic health record system embedded in the product allow for a remote patient monitoring and management.

Our goal is to make ECG diagnostic exam as simple as possible to allow the widest usage.

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How to use this manual

The Gamma Cardio CG system includes the following components:

1)	ECG Acquisition Unit	
2)	CD with the ECG Application Program to be installed on the PC	
3)	The patient cable connecting patient to the acquisition unit (Model 6726 E Fiab R or cable approved by Gamma Cardio Soft)	
4)	A set of electrodes to be connected to the patient including: ➢ 4 peripheral clamp electrodes (Model F9024 PLUS or equivalent) ➢ 6 suction chest electrodes (Model F9009 PLUS or equivalent)	
5)	A USB cable between the PC and the acquisition unit.	
6.	The End user and maintenance manual	

Table 1: Composition of the Gamma Cardio CG system

For product effective usage, we recommend reading the Chapter 1 (General Information) concerning protective measures. Chapter 2 (Intended use) describes the system features.
Before connecting the unit to the acquisition computer, it is recommended that you read Chapter 3 explaining how to install the ECG Application Program. Chapter 4 (Main Features) illustrates the ECG Application Program usage.
In Chapter 5 (First use), the user will find a detailed description of recording procedures and electrodes positioning.
More experienced users can refer to Figure 11 for a summary of the main features available in the system. Advanced features (reporting, printing, e-mail, archive patient) are described in Chapter 6 (Additional Features)

1 General Warnings

⚠ Please read carefully the instructions and the following warnings.

This section contains general warnings on the proper use of the device. Other special warnings are contained in the following paragraphs.
Failure to comply with any of the specified warnings will automatically invalidate warranty if applicable.
The manufacturer has no responsibility for damages, direct or indirect, resulting from non-compliance with General warnings or other warnings included in this manual. For additional details, please refer to the section: 7.1: Warranty and Disclaimer.
The acquisition unit shall be placed and used on a flat, stable surface, away from heat sources and areas with risks of potential fire. The system shall not be used in its packaging.
The acquisition unit must be placed far from objects experiencing easy combustion. Special attention should be considered in storage, separating the device from clothing, sheets, and anything that may generate possible fire.
The eventual conductive gel used to improve electric conductivity must be suitable for ECG examinations.
The supplied materials should be used only for functions for which they were designed, built and sold, including the packaging and this manual.
The equipment must be used in the environmental conditions of temperature and humidity specified in this Manual. The Manual describes also how to maintain equipment efficiently.
In case of storage, the device shall be placed in environments with low humidity and temperature (see operating and storage conditions).
The device should be used at environment pressure and natural air. Do not use the unit in presence of gases or flammable vapours or in oxygen rooms, even for a limited time.
The device is supplied with an enclosure completely closed but not sealed: accidental drops of liquid on the casing can seriously damage the unit.
The electrodes, cables and other accessories must be cleaned thoroughly after each use, also to avoid infections and/or contamination of the patient and/or user. The cables should also be cleaned as indicated by cable user manual.
Before each use, the user must ensure that the usage environment meets the given specifications. The ECG device should be placed and used at suitable distance from the equipment for monitoring clinical parameters and devices particularly sensitive to electromagnetic radiations. The ECG device must be used in an electromagnetic environment as specified in section 8.9 Electro Magnetic Compatibility Tables .
Before each use, the user must ensure that the ECG system works properly in its hardware and software components. The hardware and / or software functions may not be continuous and also have errors due to the specific characteristics of the computer.
⚠ When ECG recording is not performed directly by cardiologists, personnel shall carefully read section on electrodes placement (Chapter 5) and expressly inform cardiologist that electrodes have been placed by personnel with limited experience if applicable.

1.1 Operating Environment

⚠ **WARNING**, the system
- is not intended for use in the presence of flammable anaesthetic mixtures, or in environments with explosion hazards,
- is not protected against the penetration of water,
- is not to be installed in adverse environments (high humidity, direct sunlight and continuous presence of excessive dust, sulphur),
- shall not undergo sterilization processes.

⚠ The system has leakage currents in the patient that are more limited than the maximum allowed by current safety standards (IEC 60601). However, if you simultaneously connect multiple devices to the patient, the sum of the leakage currents may exceed the allowed limit.

There are no risks associated with the use of this device with pacemakers. Note that the ECG trace may appear later. Disable filters to reduce this delay.

1.2 Connecting Unit to the PC

The system has been built in compliance with current regulations on medical devices (i.e. Medical Device Directive). The acquisition unit electrically isolates the patient from the computer with a double insulation (indicated with the symbol ⧈).The unit has been designed to achieve the maximum safety level of electrical insulation (CF parts applied to the patient, symbol ⧈); this is the highest safety performance level that may be achieved by an ECG.
Note that some computers and in particular the majority of portable computers do not have metal parts which can be touched by the user and therefore they are equipped with plug without earth connection (plug with two poles). These computers do not require additional specific measures when used in medical environments.

If your computer is equipped with metal parts accessible to the user, the plug has a third terminal for grounding (three-prong plug). If regulatory requirements are not attended (for example because room grounding system is not compliant), in case of specific failures, the patient could receive a shock by touching the metal case of your PC. Such an event is independent from the use of the Gamma Cardio Soft ECG . Never use any medical device in environments where grounding is not compliant with local regulations

⚠ To avoid problems, computers with power plug including earth connection (three-prong plug) shall always be connected to a power outlet with a protective grounding compliant to local regulations.

⚠ If these PC are being used in a medical area, three options are suitable to comply to EN 60601-1, (regardless the use of the Gamma Cardio CG product:

1) PCs shall be placed outside of the patient area, i.e. so that the patient can not touch them directly or through other persons

or

2) the PC shall be connected to ground with a permanent cable that may be detached only with the use of a tool (EN 60601-1-1 BBB.201 1b).

or

3) the PC shall be connected to an outlet with additional isolating transformer

In any case, the computer shall meet the safety standards relating to information technology equipment (EN 60950) and any applicable regulation.

⚠ Warning: The system is protected against defibrillator discharge only when used with the supplied cable. In case of damages of the patient cable, use an equivalent patient cable or a cable type approved by Gamma Cardio Soft.

1.3 Before use

⚠ **Warning: do not connect the ECG acquisition unit to the computer until required by the application program, refer to Chapter 3 for installation of the ECG Application Program.**

⚠ Do not connect the metal parts of electrodes to the grounding system.

⚠ Do not use reusable electrodes other than those supplied (or equivalent types). Poor quality electrodes may degrade recording significantly.

⚠ Do not use a cable different from the supplied type. The system is protected against defibrillator discharge only using the supplied patient cable. The patient cable has also been designed to minimize electrical interference that may introduce artefacts in the ECG recording.

Make sure that the patient cable is properly connected to the acquisition unit. The patient cable must be in good conditions in all its parts and properly connected to the electrodes (refer to section 5.2). In particular, periodically inspect the patient cabls for signs of wear or damage. Damaged cables reduce the ECG quality significantly.

2 Intended Use

Gamma Cardio CG is a professional ECG certified for use in hospitals, home care and outpatient. The device shall not be used for continuous monitoring of the ECG signal, as, for example, during intensive care or emergency interventions. The device can be used in ambulances.

Regarding physical safety of the patient and operators, the system has been designed with performance that are much higher than required by current standards (IEC / EN 60601, IEC / EN 60601-1, IEC / EN 60601-2-25, IEC / EN 60601-1-2). Regarding the clinical validation, the diagnostic performances are guaranteed through the compliance to ANSI AAMI EC 11 standard.
The instructions for use are outlined in the following figure.

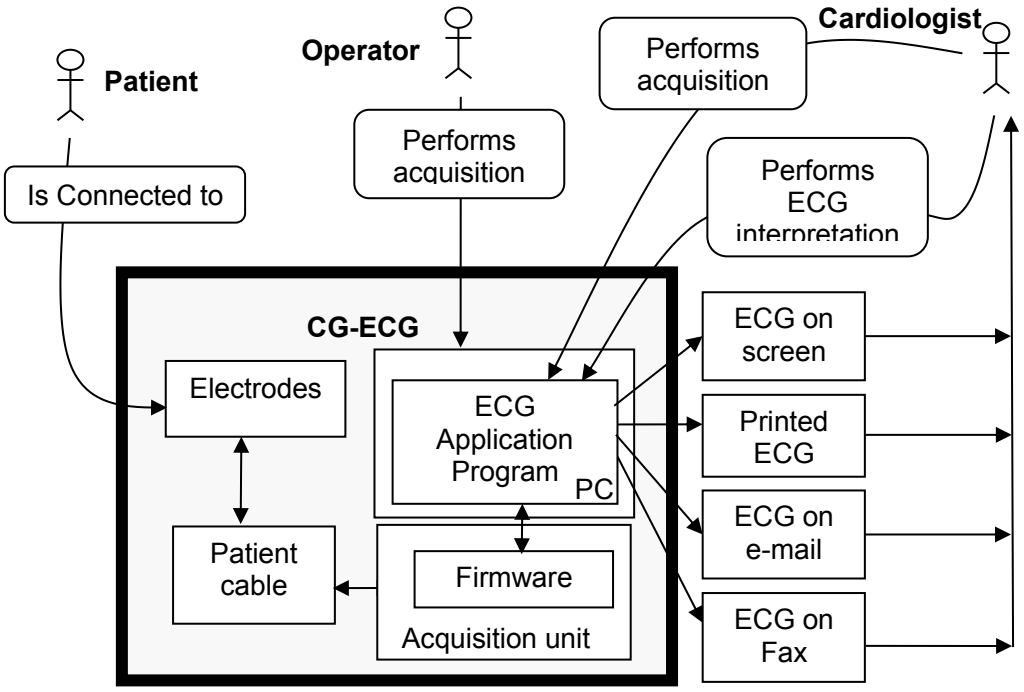


Figure 1: System usage

The operator places the electrodes on the patient and records the ECG through the user interface available on the ECG Application Program. The ECG recording is stored on computer disk or on other available media (USB devices, network-cloud areas, ...) The ECG file can be transferred later to a qualified doctor for reporting. The mail system embedded in the ECG Application Program may be also used to send ECG recording

The operator that records the ECG can be a doctor, a nurse and in general a properly trained user. Note that the patient can record the ECG by himself through the help of other personnel for electrodes placing. In this case, the role of the operator coincides with the role of patient.

⚠ **<u>WARNING:</u> the ECG interpretation can be performed only by specialist medical doctors.**

For rapid interpretation, the specialist can use:

1) the display of the ECG on the computer screen;
2) the ECG printed on paper;

3) the ECG sent by fax. The operator can send the recording to a specialist through the fax printing function of the ECG Application Program when the PC is connected to a PSTN line and the computer has the fax application properly installed;
4) the display of the ECG file received by e-mail, stored on removable media or on network-cloud drive.

The ECG Application Program allows sending ECG recording via e-mail and/or it can store the recording into a media such as USB pen drive, hard disk, CD-ROM, storage area network...). The ECG can be stored in a standard format (Acrobat PDF) or in the Gamma Cardio Soft proprietary format.

To show ECG recording, specialists require a PC containing:

- Acrobat Reader (freely available on Internet) to display the standard format (PDF)

or

- The ECG Application Program to display the proprietary format.

With the Gamma Cardio Soft ECG Application Program, the specialist or the operator has the possibility apply or remove filters to eliminate artefacts or to delete parts of the ECG even after recording have been performed. The specialist can also use special diagnostic tools for rapid interpretation included in the program.

The specialist can save the ECG with interpretation in the patient archive included in the ECG Application Program. It is possible to send ECG and the associated interpretation via fax or e-mail directly from the ECG Application Program. Alternatively, the report with the interpretation and the EGG records can be printed or saved on the computer.

3 Installation

3.1 Minimum Computer Requirements

The Gamma Cardio Soft ECG Application Program requires a PC with the following minimum requirements:

1) Windows XP, Windows Vista, Windows 7, Window 8 or later;
2) 256 MB RAM minimum;
3) video card with minimum resolution of 1024 × 600;
4) a free USB port

The e-mail capability of the ECG Application Program may also rely on an e-mail system installed on PC compliant with MAPI (Microsoft Windows Outlook Express, Lotus Notes, ...) and the availability of an Internet connection.

A fax-modem card is required to use the fax function. In this case, the fax printer application has also to be installed on the PC. Follow the instructions for the operating system to install Fax. On the XP operating system, for example, you must:

1. Open "Add or Remove Programs" in the Control Panel.
2. Click Add or Remove Windows Components.
3. In Windows Components Wizard, select the Fax Services check box, and then follow the on screen instructions.

3.2 Installation procedure

⚠ **Do not connect Acquisition unit before installing the software.**

Before connecting the acquisition unit, insert the installation CD into the computer.

If you accidentally connect the acquisition unit to the PC before installing the ECG Application Program, unplug the unit and wait a few minutes and then proceed with the insertion of the CD. After a few seconds, the computer will display the installation program.
If you don't have a CD reader on the specific PC, copy all the CD on an USB-network drive.

If the installation program does not run automatically, (or if software is not on CD)

1) Click on My Computer
2) double-click the icon for the CD Rom (or the drive where the software is located)
3) double click on the file: Setup_GammaCardioCG.exe.

Follow the installation instructions that appear on the screen. When prompted, connect the acquisition unit to the computer as follows.

3.2.1 Connecting the unit to the computer

Connect the small connector of the USB cable (left part of Figure 2) to the acquisition unit

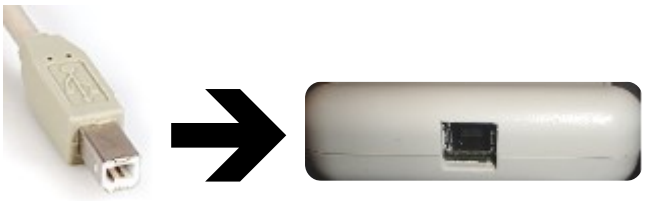


Figure 2: Connect the USB cable to the acquisition unit

Connect the large connector with rectangular section to an USB port on your computer.

3.3 Running the ECG Application Program

The installation program places the icon

on the desktop and the menu "Gamma Cardio CG" among the applications recallable from the start button

if applicable for the specific operating system.

To start the ECG Application Program, double-click on the desktop icon or start the program by pressing the button

. For older Windows operating systems, select the menu programs and locate the menu "Gamma Cardio CG", where the program Gamma Cardio CG can be started

.

4 Key Features

To access the main features, simply press the associated buttons available on screen of the ECG Application Program. These buttons have similar appearance and behavior to the buttons present in the ECG physical devices. To select the functions associated to the buttons:

1) place the mouse arrow on the button to be selected;
2) the arrow will turn into a virtual hand and the button will be selected (the button color will become lighter;
3) press the left mouse button to push the selected button/function.

For computers with touch screen simply use the finger to select the required function. The features are grouped spatially in a consistent manner as shown in the following figure.

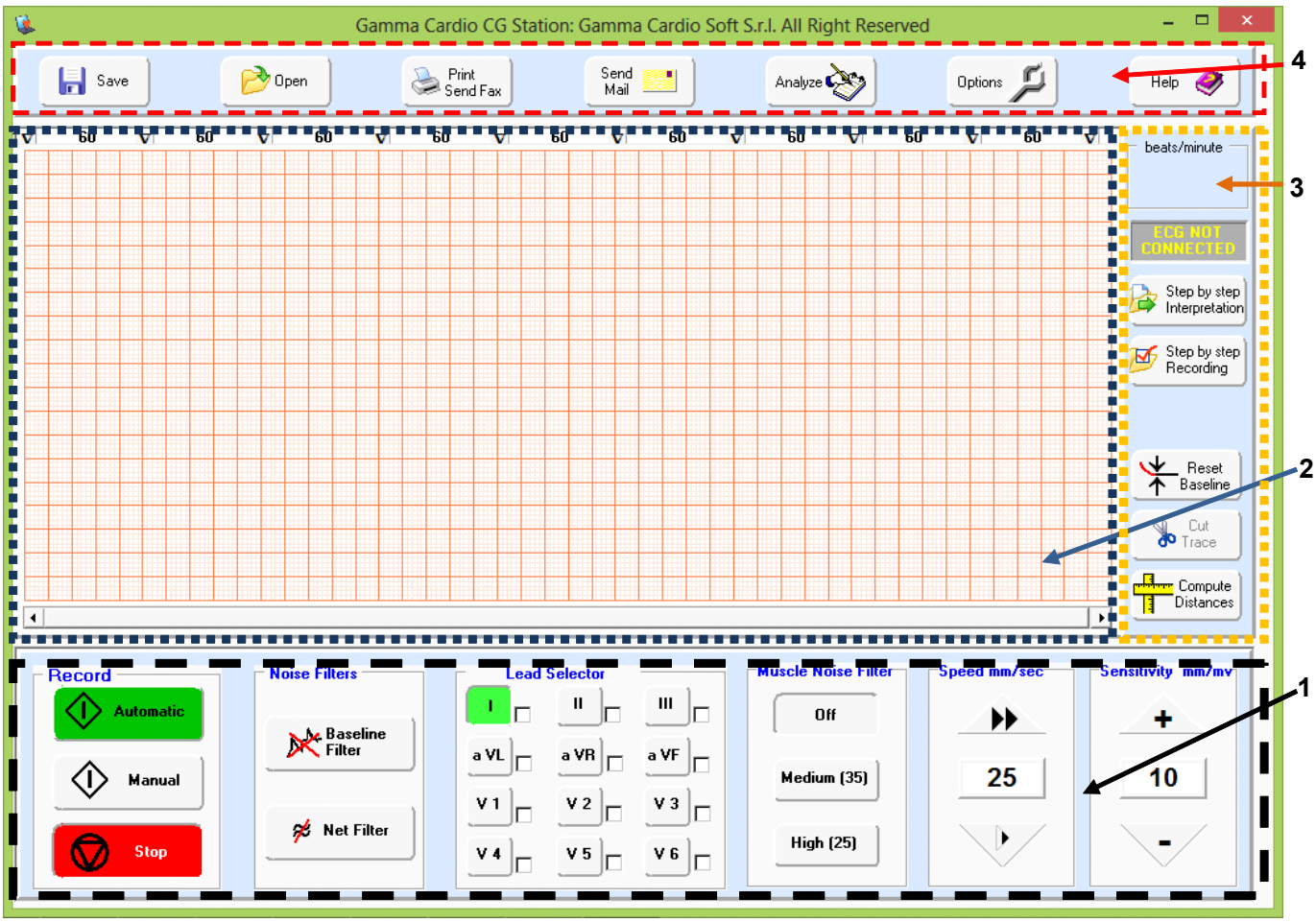


Figure 3: Detail of the main screen

The main screen is divided into four areas:

1) the **command keyboard** to control the electrocardiograph (screen bottom side enclosed in the area marked with 1),

2) the **display area** where ECG recordings are shown (screen left side enclosed in the area 2)
3) the **toolbox area** (screen right side enclosed in area marked with 3)
4) the **advanced command** area of (top screen enclosed area marked with 4)

4.1 Commands Keyboard: bottom area of the screen

The keyboard contains the command buttons usually found in the conventional electrocardiographs. The keyboard layout has been designed to resemble the conventional electrocardiographs.
The keyboard contains the buttons controlling recording in the left panel.
In particular:

is used to automatically record a predefined number of seconds of all the ECG 12 leads. The system will start recording one lead at time from D1 to V6.

Warning, pressing this button will delete the previous ECG recording hold in memory if it has not been saved on disk.

allows recording the selected lead until the operator presses the Stop button. The selected lead is highlighted in green in the "Lead Selector" Panel. To record a specific derivation, press the button corresponding to the lead (or click the button with the left mouse button) and then press the Manual button.

Warning, pressing the Manual button will delete the current lead recording that will not be recovered unless previously saved on disk. The Manual button selection does not delete the data and reports for the specific patient and do not delete any other derivations stored in memory.

interrupts the ECG recording either in automatic mode, either in manual mode.

In manual recording mode, the Lead Selector panel shown below is used to choose the lead derivation. In Automatic mode, the Lead Selector panel shows the derivation under recording.
If the system is not recording ECG (indicated with the Stop button pressed), you can display a specific lead by pressing the corresponding button on the Lead Selector Panel.

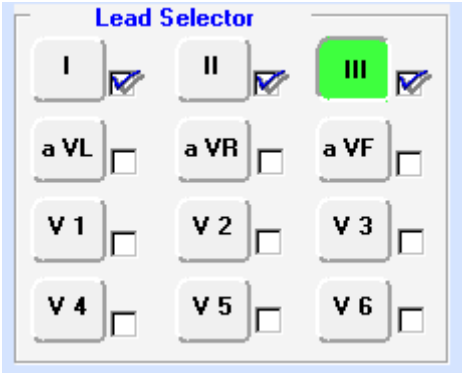


Figure 4: Lead Selector Panel

The symbol ☑ to the right of each single lead button in the lead selector panel shows that the corresponding lead has been recorded in memory. For example, in Figure 4, leads I, II and III have been already recorded.

The arrow buttons for the Sensitivity and Speed (Figure 3, bottom right) allow for changing speed and sensitivity as in the conventional electrocardiographs with the difference that sensitivity and speed can be changed also when the lead has been already recorded.
The arrows buttons of speed increase or decrease the scrolling speed of the ECG pen as in conventional ECG devices. This allows having horizontally enlarged or shortened ECG traces. Similarly, the sensitivity buttons allow you to change the vertical scale of the ECG recording. The system presets the standard speed and sensitivity (sensitivity = 10 mm / mv and speed = 25 mm / sec). Double clicking on the speed/sensitivity indications will revert to the standard values.
Available recording speed are 5, 10, 25, 50, mm /second + 75, 100, 200 mm /second (zoom recording speed). Available Sensitivity values are 5-10-20 mm/mv + 30, 40, 50 mm/mv (zoom recording sensitivity).

It is worth noticing that sensitivity and speed can be changed also after recording. Using this capability, it is possible to:

- show enlarged details of the ECG morphology
- display many consecutive waves for evaluating rate and regularity of heartbeats.

4.2 Noise reduction and artefacts

The noise filters allow reducing artefacts superimposed to the ECG tracing. Artefacts are mainly generated by:

- interference from the mains supply;
- patient muscle tremors;
- instability of the isoelectric line.

4.3 Interference from Power line

When interference from the power line is significant, the ECG recording contains an additional signal oscillating at a frequency of 50 times per second (50 Hertz or 60 Hertz according to the local power line frequency) as shown in the example of Figure 5.

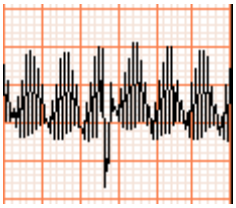


Figure 5: Lead V 1 with artefacts from power line

The possible reasons from such interference are due to:

1) high electromagnetic fields generated, for example, by other medical electrical equipment or neon lamps;
2) high voltage electric cables close to the patient;
3) poor electrode-skin connection;
4) faulty patient cable;
5) poor connection between the electrodes and patient cable.

If the problem is due to the presence of voltage conductors or neon lamps, such elements may be placed far from the patient area.
The poor electrode-skin contact can be improved by hydrating skin where electrods are placed or by using conductive paste gel.

The conductor fault may be identified since interference completely hide the ECG signal. It is recommended to replace patient cable if it is damaged. To find the critical lead connection, refer to the table below and to the section 5.2.

if the interference is present	**check the plug marked with the label**	**verify the electrode positioned on**	**the electrode has the colour:**
on all the 12 leads	N	right ankle	Black
on all leads except I	F	left ankle	Green
on all leads except II	L	left wrist	Yellow
on all leads except III	R	right wrist	Red
only a precordial derivation V x	C x	precordial position C x (see section 5.3)	No color on suction electrodes

Table 2: Identification of the critical electrodes / cables

If artefacts cannot be eliminated, insert the net filter by pressing the corresponding button

. This operation can also be performed after recording. For example, activating the line filter on the ECG of Figure 5 will eliminate interference showing the ECG tracing as in the following figure.

Figure 6: Lead V 1 with artefacts from mains supply (figure 5) and net filter activated

4.3.1 Isoelectric Line Instability

The isoelectric line is the straight line obtained in absence of electrical activity. This line should be horizontal. During recording, the ECG waveform moves cyclically with respect to the isoelectric line due to the electrical activity of the hearth.
When interference is on the isoelectric line, the ECG waveform will have a non-regular trend that is not parallel to the horizontal axis as shown in the examples of the following figure.

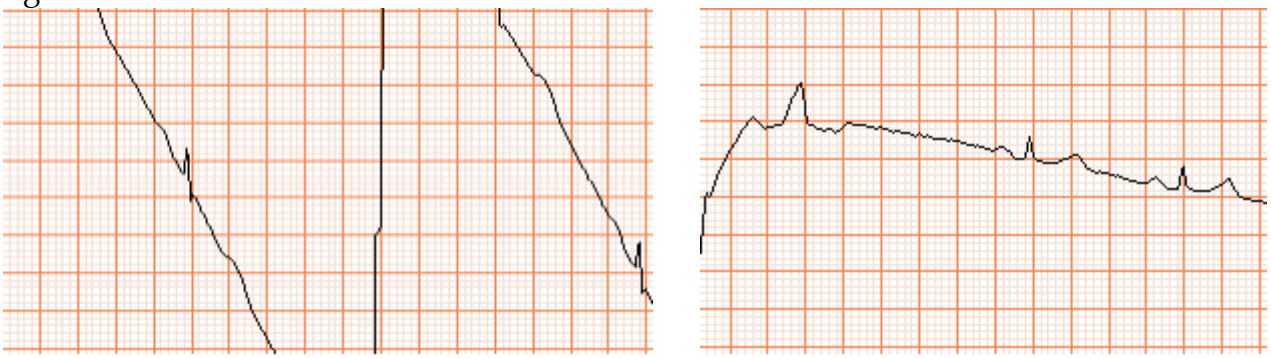
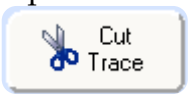
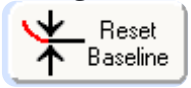


Figure 7: ECG with instability of the isoelectric line

These artefacts are generally caused by:

1) inadequate connection between the cable and the electrode or between the electrode and the skin;
2) polarization of the electrodes especially at the beginning of the ECG tracing;
3) movements of the patient.

In case 1), check for possible critical connections on patient cabling referring to Table 2. If necessary, repeat the procedure for the electrode displacement, moistening and rubbing the skin contact area.
In the other two cases, the problem is usually limited to a specific area of the ECG and therefore, after recording, it is possible to delete the unsuitable ECG parts affected by artefacts using the button 

. During recording, if the ECG is slowly approaching to the horizontal isoelectric line as in the right part of the previous figure, it is possible to quickly restore the horizontal behaviour by of pushing the button 

.

When the problem cannot be eliminated, the Net filter may greatly reduce the artefact (button

).

4.3.2 Muscle tremor

The EGC recording affected by noise due to muscle tremors appears as in the figure below

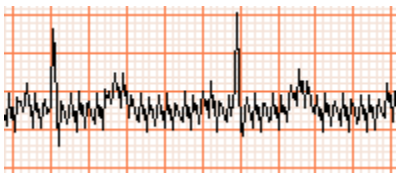


Figure 8: ECG with artefacts due to muscle tremors

The ECG shows a behaviour that resembles the classic saw-tooth pattern.
Muscle tremor is caused by unintentional patient muscle activity due to:

1) perceived cold environment;
2) irritability;
3) too narrow examination table;
4) patient disease (e.g., Parkinson's).

If the causes cannot be eliminated, it is possible to insert the Muscle Noise Filters to 25 (high effect) and 35 Hertz (average effect). The filter at 25 Hz has a deeper noise reduction compared to the 35 Hertz.

Warning: Muscle noise filters have the effect of rounding peaks (such as the QRS complexes) Consider this effect in the ECG interpretation.

4.4 ECG Display

The ECG display shows the ECG similarly to the physical ECG printers. The top bar (Figure 9) contains placeholders (i.e. triangles) that in absence of tracing, are equally spaced at a distance of one second. The number of beats per minute is placed between two placeholders: 1 second distance corresponds to 60 beats per minute according to the formula for beat frequency calculation:
Beats per minutes = 60/(average distance in seconds between two QRS complexes)

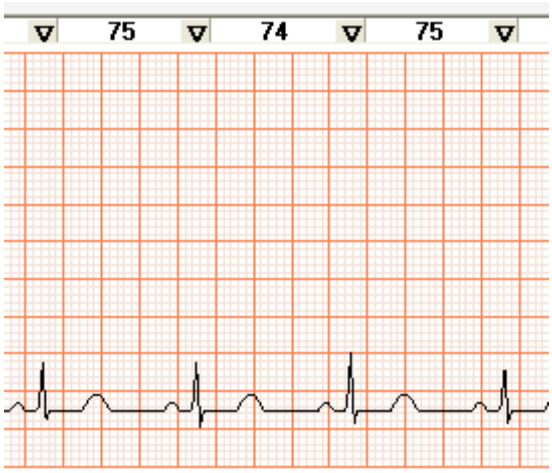


Figure 9: ECG with placeholders indicating the number of beats per minute

When an ECG is displayed, pacemakers are aligned to QRS complexes. This allows a quick computation of the cardiac frequency rhythm.

4.5 Toolbox area

This area contains tools for 1) deleting parts of the recording, 2) measuring distances 3) measuring current heart frequency rate.
When the Gamma Cardio CG system recognizes the QRS complexes, average heart frequency rate is displayed with a blinking heart symbol synchronized with hearth systoles.

4.5.1 Deleting ECG parts

To delete ECG segments within a derivation:

1) place mouse pointer over the starting point of the section to be deleted;
2) hold down the left mouse button and drag the mouse to the end point of the section to be deleted;
3) release the mouse button and press the button

.

⚠ **WARNING:** It is recommended to remove only segments including complete beats (for example from the beginning of a P wave to the beginning of the following P wave of the next beats) so as not to introduce discontinuities in ECG recording or artificial artefacts.

4.5.2 Deleting leads from the PC memory

To delete the selected lead or all the recorded leads not yet saved on disk, press the button

without selecting any ECG segment. The ECG Application Program will show a window with options for deleting recorded leads in memory. Note that this procedure does not delete leads saved in disks.

4.5.3 Record a new ECG

When the button

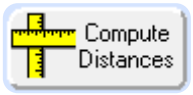
is pressed, the eventual ECG stored in memory is deleted and a new ECG is recorded.

The ECG stored in memory may be deleted pressing the button

and selecting the option "new ECG" included in the window that is displayed.

4.5.4 Measurement of intervals

To measure the horizontal and vertical distance between two points:

1) press the button 

;
2) place the mouse pointer on the starting point and click with the left mouse button;
3) place the mouse cursor on the second point and click with the left button.

The window of Figure 10 will appear indicating the vertical distance (in millimeters and millivolts) and the horizontal distance (in millimeters, seconds, and in beats per minute) between the two selected points.

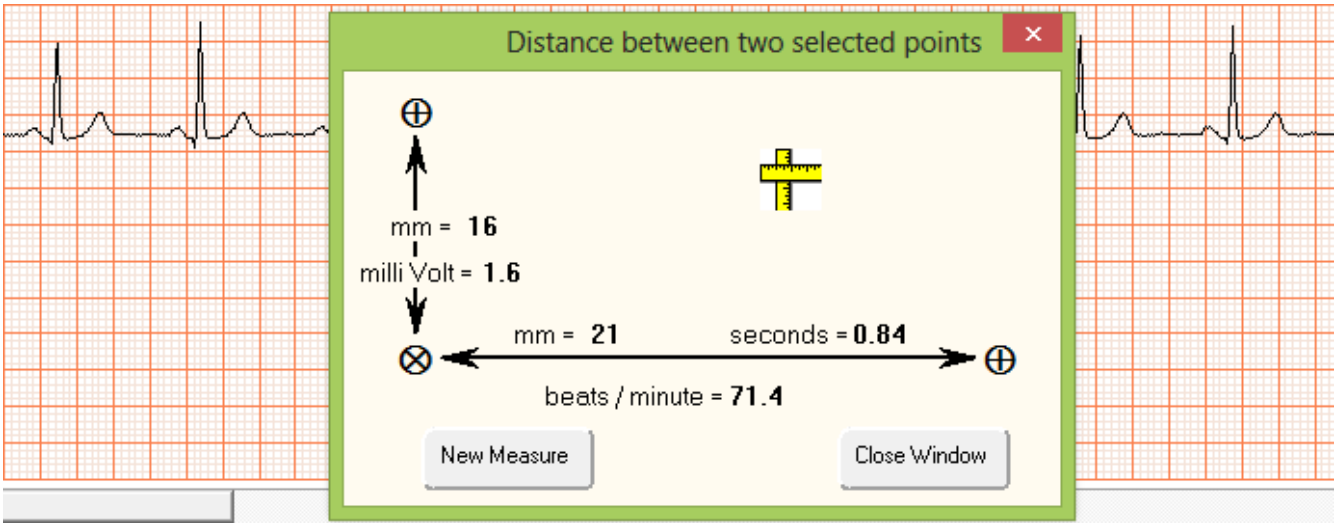


Figure 10: Tool for measuring distances

5 First use

The following figure shows the steps required to use the ECG system.

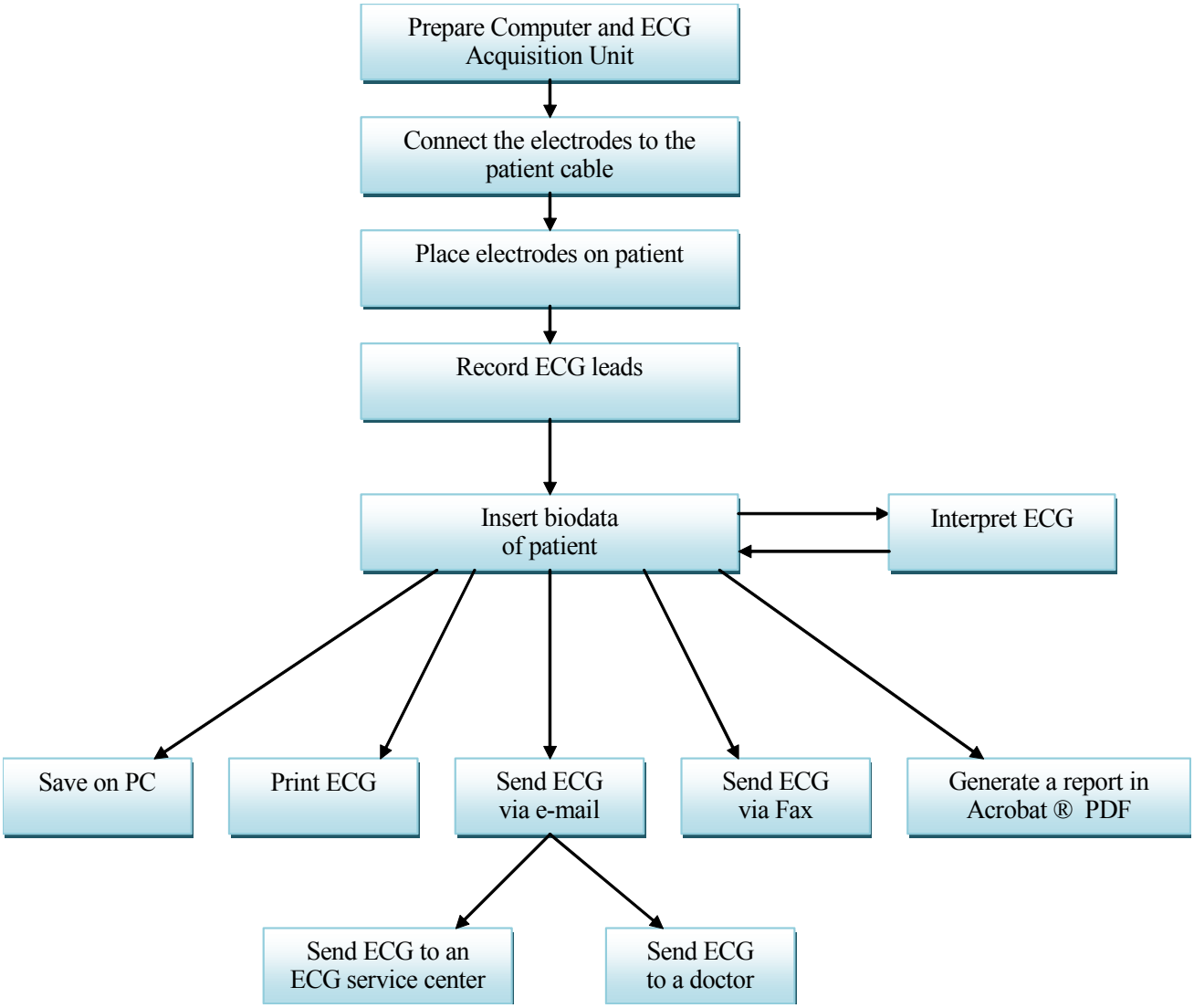
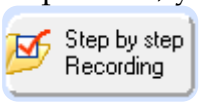

Prepare Computer and ECG Acquisition Unit
Connect the electrodes to the patient cable
Place electrodes on patient
Record ECG leads
Insert biodata of patient
Interpret ECG
Save on PC
Print ECG
Send ECG via e-mail
Send ECG via Fax
Generate a report in Acrobat ® PDF
Send ECG to an ECG service center
Send ECG to a doctor

Figure 11: Gamma Cardio CG usage

The following paragraphs describe the steps outlined in the previous figure.
For a fast acquisition, you can use the step by step procedure that simplify ECG recording.

Push the 

button on right side of the main screen window. The following frame will appear. Perform each step in order to finalize an ECG recording.

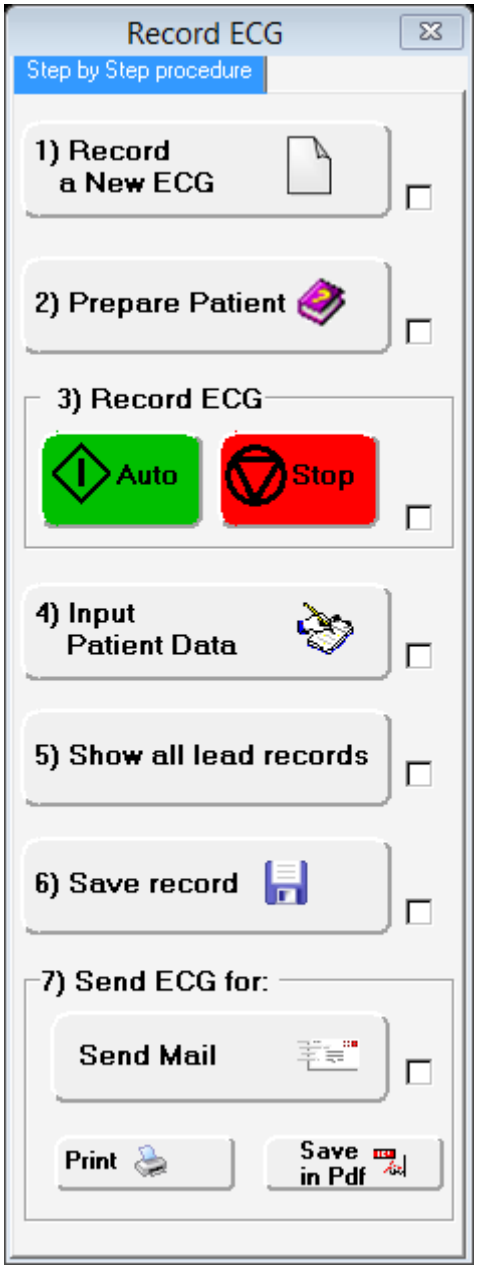


Figure 12: Step by step Recording procedure

5.1 Preparing the ECG system

To record an ECG, do the following before placing the electrodes on the patient:

1) switch on the computer;
2) run the ECG Application Program using the icon

3) after few seconds, the ECG Application Program window shown below will appear on the screen.

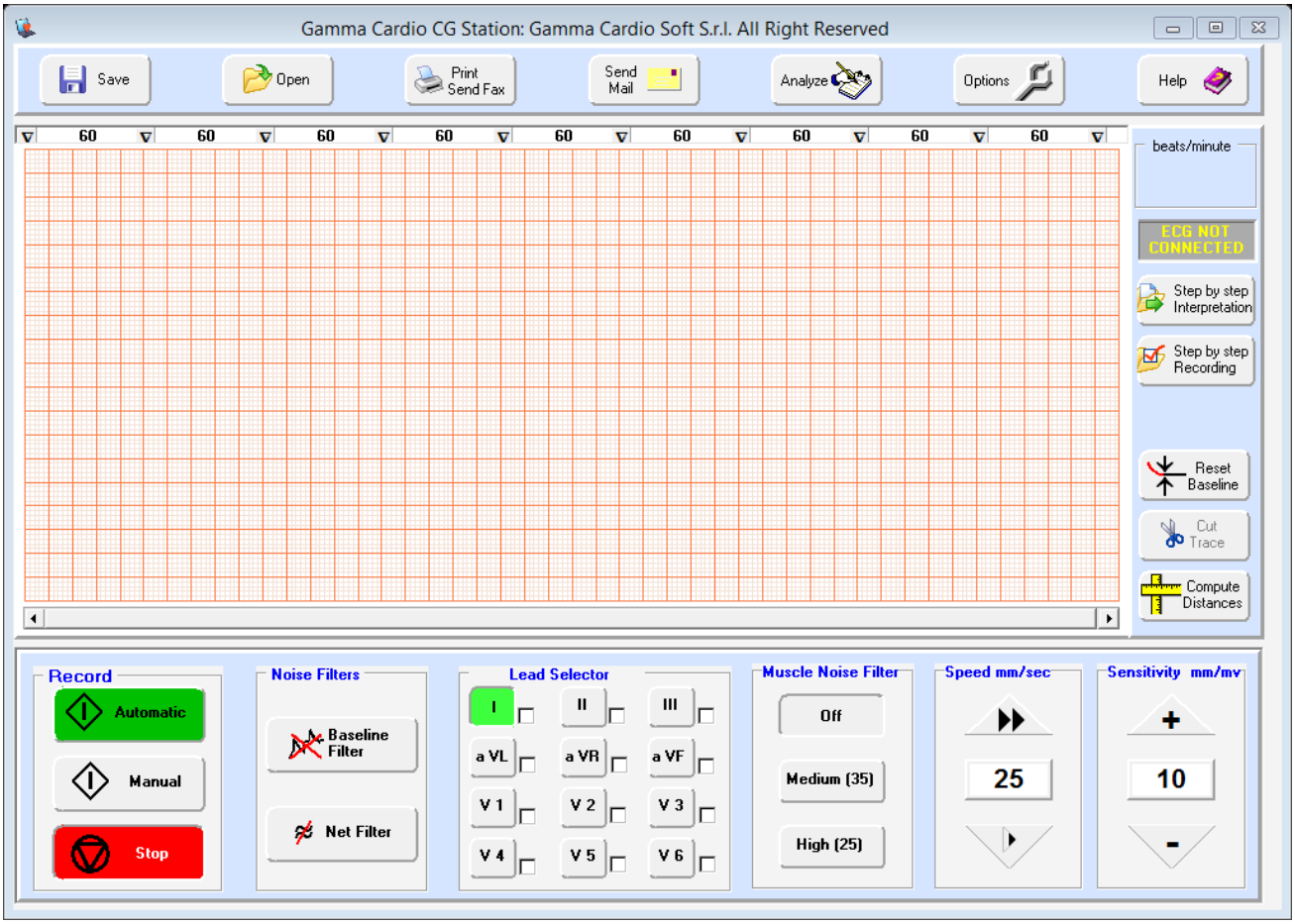


Figure 13: Main application window

4) connect the Gamma Cardio CG Acquisition Unit to your PC using the supplied USB cable (see paragraph 3.2);

⚠ **Warning:** After connecting the PC to the acquisition unit, verify that the message

disappears from the screen. If this message is still displayed on the screen, the ECG device is not connected. In this case, check carefully the PC device connection.

3) Connect the patient cable to the acquisition unit

Figure 14: Connection between patient cable and acquisition unit

The connection of the electrodes to the patient cable and the electrodes placement on the patient are the most critical steps for an effective ECG recording. These steps require greater attention by non-expert users. In the following paragraphs, this operation is then

described in details. An experienced user can directly refer to Figure 14 and Figure 15 for the correct placement of the electrodes.

5.2 Connecting the electrodes to the patient cable

The Gamma Cardio CG device includes four high quality reusable silver silver-chloride clamp electrodes for connection with the limbs and 6 high quality reusable silver silver chloride suction chest electrodes. It is also possible to use disposable electrodes using various adapters as for example the pin clips that can be introduced into patient cable plugs: . To record a standard resting ECG (12 leads), 10 electrodes must be positioned on the patient, four at the ends of the limbs and six precordial electrodes on the chest.

The first step consists of connecting the electrodes on the patient cable plugs. The clamp electrodes are connected to the plugs according to the following combination of colors:

European IEC standard colour electrode	must be connected to the jack with color band	the plug bend is marked by the letter	the electrode should be connected to
the green electrode	Green	F	(Foot) Left Ankle
the black electrode	Black	N	(Neutral), Ankle right
the red electrode	Red	R	(Right), Right wrist
the electrode yellow	Yellow	L	(Left) Left Wrist

Table 3: Connection between electrodes and the patient cable

Insert the correct plug of the patient cable into the hole of the electrode by tightening the screw so as to ensure an effective contact.

The suction electrodes must be connected to the six remaining pins marked by the initials C1, C2, C3, C4, C5, C6.
Make sure that the screw is properly tightened on each suction electrode so as to ensure an effective contact. Note that American AHA standard has different color codes.

5.3 Electrodes placement

An inadequate placement of the electrodes is a main reason for poor quality ECG recording with eventual artifacts as described in section 4.2 (interference from power line, instability of the isoelectric line, muscle tremors). It is the highly recommended to perform the following steps with care.

Before placing the electrodes:

1) place patient on a wide and comfortable bed to prevent muscle contraction that may occur to retain arms and legs on the bed. In case of muscles contraction, artifacts may be superimposed on ECG recording;
2) uncover patient chest eliminating bracelets and watches from patient wrists;
3) verify that the patient is not in contact with metal structures of the table or other metallic objects;
4) ensure that the ankles are free from garments in order to allow the application of the electrodes.

Before placing electrodes, wipe the contact skin area with a cotton wool soaked in disinfectant or water in order to moisten it.

In a resting electrocardiogram, four clamp electrodes have to be placed on the ankles and wrists.

For the electrodes placed on the wrists, moisten the external face (about 10 cm above the wrist). For the electrodes placed on the ankles, moisten the external face (about 10 cm above the malleolus).

Place each electrode so that the conductive plate is in contact with the previously moistened skin areas. The following figure shows the position of the limb electrodes based on their color

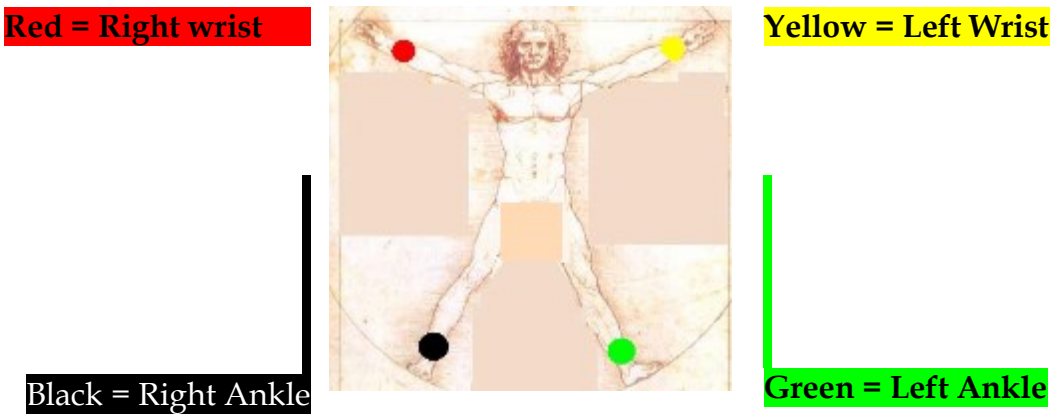


Figure 15: Peripheral electrodes positioning

The standard positions of the suction electrodes (precordial) are summarized in the following table:

Code of the terminal electrode (European IEC standard)	Derivation name (USA)	Position the patient
C1	V1	4th left intercostal space at the right parasternal line.
C2	V2	4th left intercostal space at the left parasternal line.
C3	V3	halfway between V2 and V4
C4	V4	5th left intercostal space at the mid-clavicular line.
C5	V5	5th left intercostal space at the anterior axillary line.
C6	V6	5th left intercostal space at the mid-axillary line.

Table 4: Standard position of chest electrodes

The next figure shows the electrode placement in more detail:

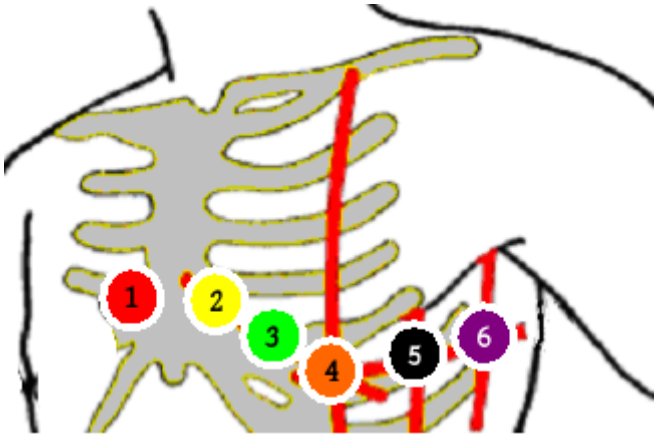


Figure 16: Standard position of precordial electrodes

For a faster positioning of precordial electrodes, consider the following indications:

- C1 and C2 to the right and left of the sternum, about 3 cm above the sternum (xiphoid process) (IV intercostal space).
- C4 5th left intercostal space at the mid-clavicular line.
- C3 at the midway point between C2 and C4
- C5 and C6 on the same horizontal level of C4 (fifth intercostal space) but respectively on the front and the left axillary line on the line media.

Note, however, that the ECG recording is unaffected by millimetric errors in positioning the electrodes. The next figure shows the placement of the electrodes for an adult.

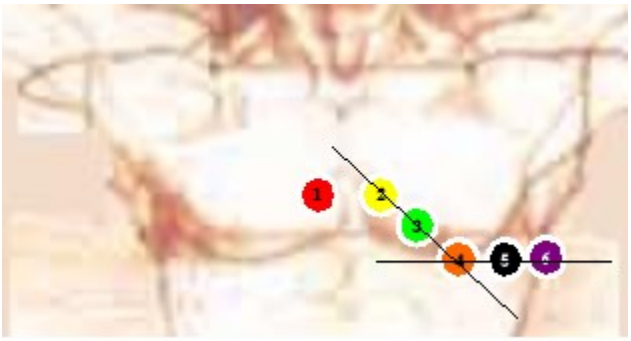


Figure 17: Precordial electrode placement on adults

To apply the precordial electrodes, hold the suction cup, squeeze the rubber ball and then, press the electrode until a good adherence of the contour of the cup on the skin is obtained. Then release the rubber ball.

A bad contact between the electrode and skin introduces artifacts as shown in section 4.2.
In case of excessive hair in the chest area, the use of a conductive paste gel may help improving conductivity between the electrode and the skin. In the most critical cases, chest area has to be shaved.

5.4 ECG recording

The automatic mode may be used to quickly record a new ECG: press the button

and wait until all the 12 leads are recorded.
It is suggested not to activate noise filters during recording to avoid that the ECG signal slow down on the display for computers with limited performance. The anti-interference filters can also be activated after ECG has been recorded.

When recording only the peripheral leads (I, II, III, aVL, aVR, aVF), automatic recording can be stopped by pressing

.

5.4.1 Reducing artefacts

Make sure that ECG recording does not include significant artifact as described in paragraph 4.2 (Noise reduction and artefacts). To do this, use the lead selector panel to display all the leads.
It is recommended to repeat recording for leads including significant artifacts by using the manual mode (button

). Follow the procedures in section 4.2 to eliminate artifacts (improving skin-electrode and verifying electrode-cable connections) and check the effectiveness of these procedures on ECG recording quality.

Press the Stop button at the end of the manual recording. If artifacts are located in a limited area, the cut trace button

may be used to eliminated selected areas of recording.
If the causes of artifacts cannot be eliminated, insert anti-interference filters.

6 Additional Features

All the twelve leads can be shown using the

button.

This button will show a report where ECG recording quality can be verified as shown in the following figure.

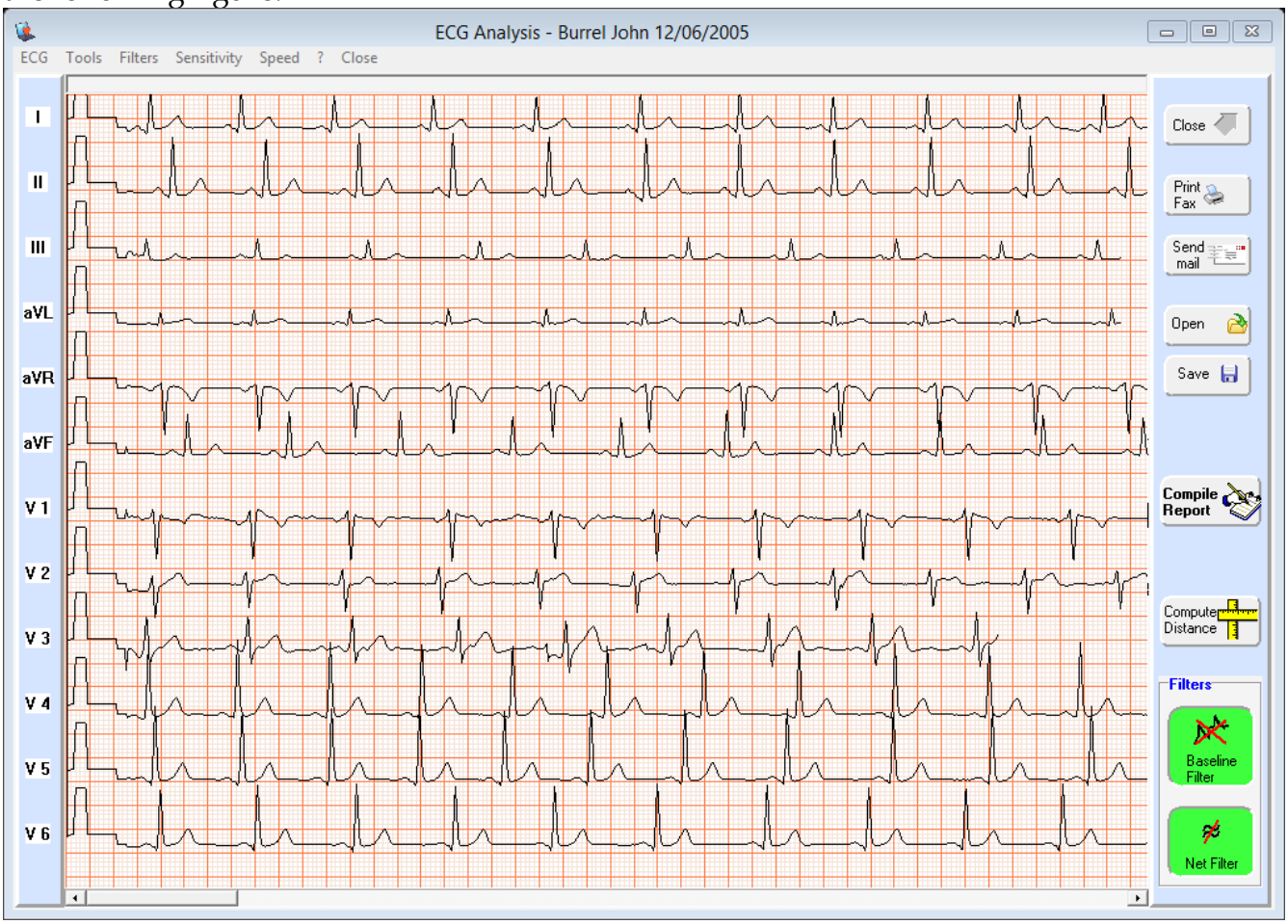


Figure 18: Simultaneous display of 12 leads

If the isoelectric line is not sufficiently horizontal leads may overlap. In this case, insert the anti-drift baseline filter. Within this report you can also include/exclude filters or change the sensitivity/ speed of the recording after recording. The ECG waveforms will be updated accordingly. This process is reversible, that is, no degradation is obtained in changing sensitivity/ speed or in changing filter configuration.

⚠ **WARNING:** the 12 leads are not simultaneously recorded and therefore leads are related to different time instants. For this reason, the QRS complexes of different leads are not aligned. Consider this circumstance when interpreting the ECG.

6.1 Entering patient data

Before saving ECG on the hard disk or on the network, it is suggested to enter patient data. In this way, the saved ECGs of a specific patient will be easily retrieved.

To enter patient data:

1) Press the button Compile Report available after pressing Analyze
2) Enter data into the form shown in the following figure

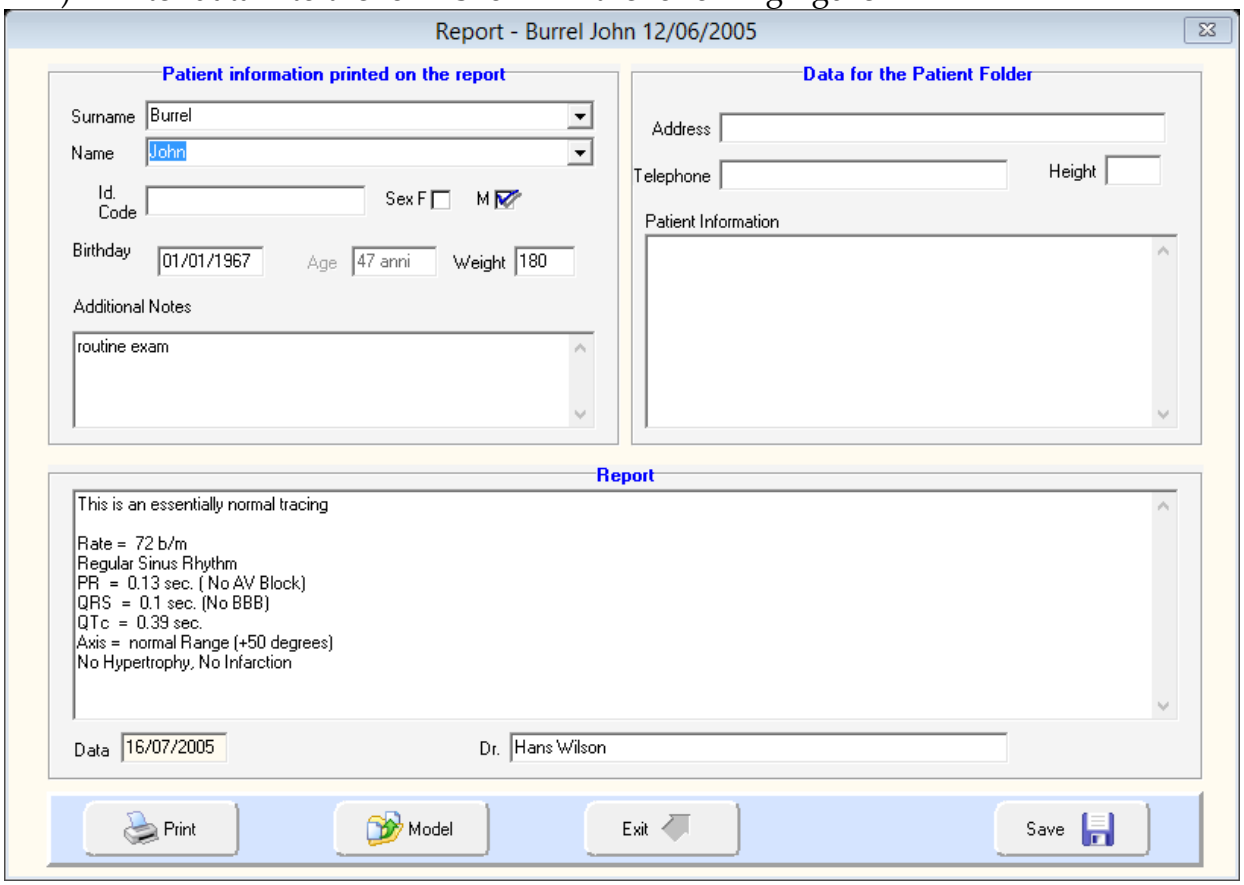


Figure 19: Form for patient data entry

⚠ **WARNING:** The ECG interpretation must be completed by qualified personnel.

If the interpretation is performed after recording as in the case of a telemedicine scenario, it is suggested to include all relevant data for interpretation (health, motivation examination, ...) in the "Additional Notes" area. This information will be included in the report containing the ECG recording.

⚠ **Warning:** press the button Save to save the ECG recording on permanent memory (hard disk, network storage, ...). This action will also update the internal database. Without this operation, the ECG will be deleted after the following ECG recording.

6.2 Patient database

The Gamma Cardio CG manages saved reports automatically on the database.

The database can be accessed by pressing Options on the main form and clicking on the tab "Patient Database" The form shown in the following figure, is divided into four areas. After selecting a patient in the upper left area, the other three areas will be completed automatically with the associated data. In particular, the upper right area will contain the data of the patient, the lower right area will contain the ECG associated to the patient and the lower right area will contain the interpretation for the selected ECG.
The database is automatically updated when an ECG is saved or deleted.

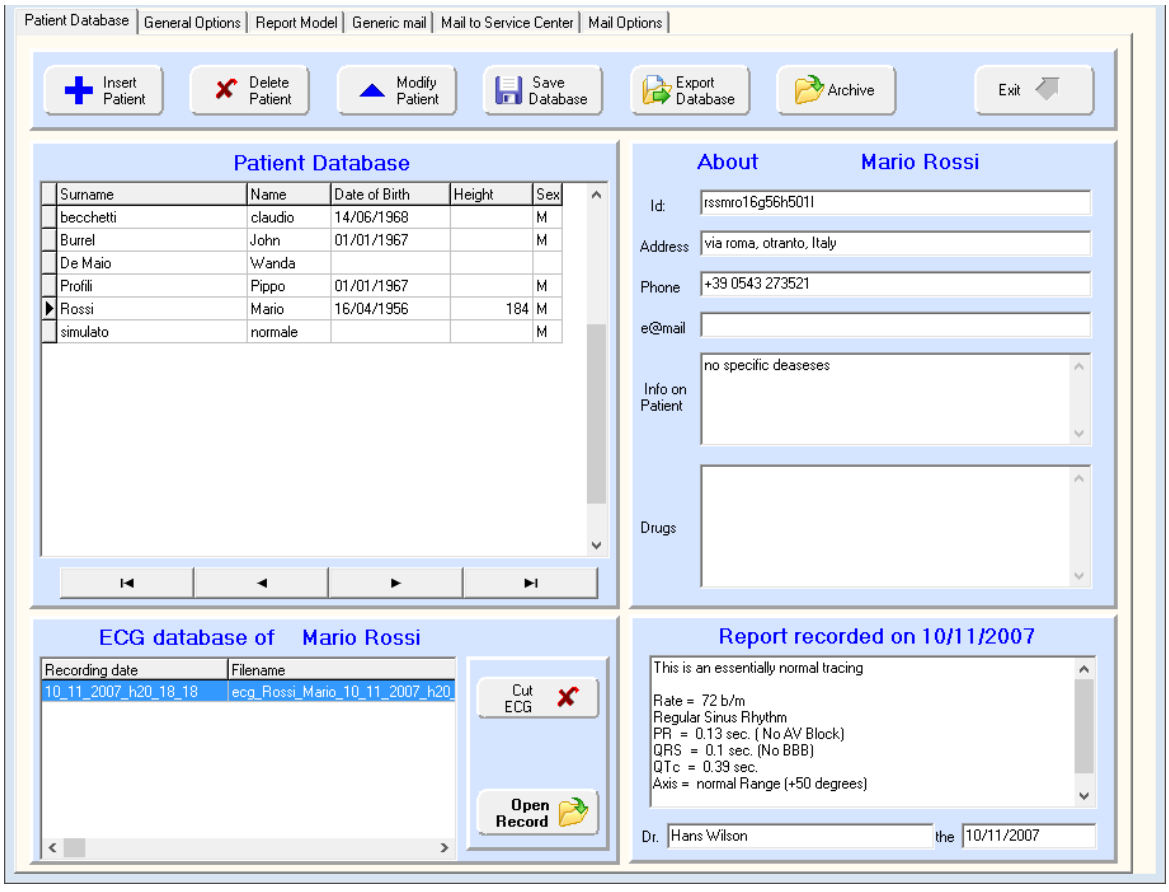


Figure 20: Patient Database

6.3 Loading a saved ECG

The ECGs saved on the computer or on the network can be loaded using the button Open. The system will display the usual Windows screen for opening files. Note

that the names of the ECG files have a structure like “ecg_Surname_Name_Date_Time.bce”, where the date and time refers to the time when the ECG was recorded: for example: "ecg_Smith_Tom_12_07_2013_h16_50_36.bce"

6.4 Reporting

The Gamma Cardio CG includes a module for professional printing. The generated report includes the patient, data, the 12-lead ECG and the interpretation. The following figure shows an example of such report. The report can be printed, sent via fax or saved in pdf format.

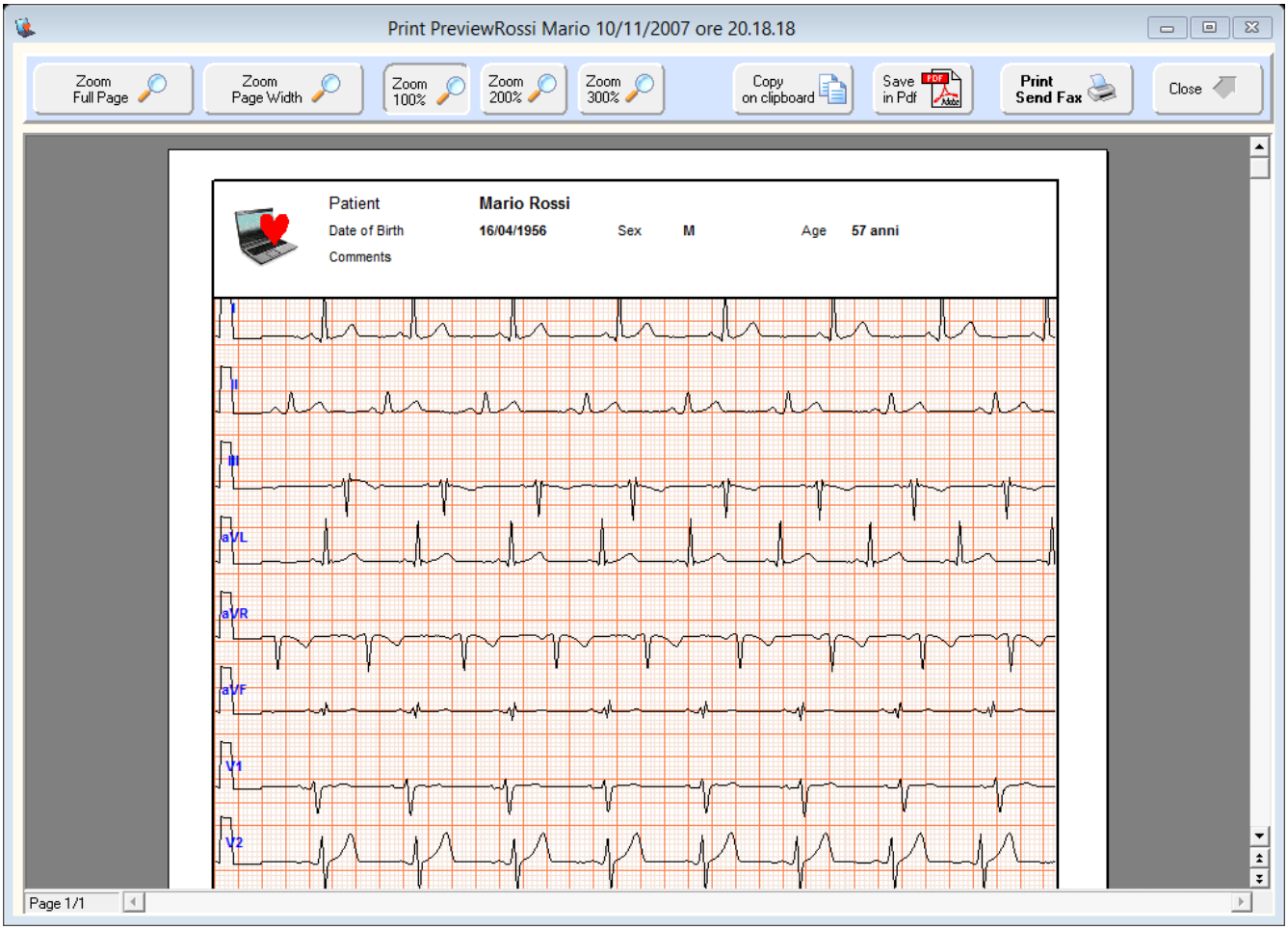


Figure 21: Example of a printed report

6.5 Usage with defibrillator

The Gamma Cardio CG system is protected by defibrillator discharges
provided that the supplied cable or a cable approved by Gamma Cardio Soft is used.

At this aim, it is recommended:

1) to follow the instructions of the defibrillator;
2) to place the defibrillator paddles in areas well separated from the ECG electrodes;

3) not to touch the body of the patient during defibrillation

The Gamma Cardio CG System will restore the ECG waveform few seconds after defibrillator discharge. To restore the isoelectric line more quickly, press

.

6.6 Other features

The Gamma Cardio Soft system allows also:

- sending the ECG to an ECG Interpretation Services Centre and/or to Doctors cardiologists using the integrated email system;
- printing professional reports;
- saving the ECG in Acrobat PDF format;
- sending the ECG via fax;
- the automatic storing of reports in the database.

These functions are available through the buttons on the advanced features placed in the right area of the form shown in Figure 17 or in the top area of advanced commands of Figure 3.

For the use of an external e-mail management program, it is necessary that the computer is equipped with an e-mail application compliant to the standard MAPI (Microsoft Windows Outlook Express, Lotus Notes, ...) and that there is the availability of an Internet connection.

The fax function can be used if the PC is equipped with a Fax modem card and the fax printer application is installed.

7 Maintenance

The Gamma Cardio CG does not require special maintenance operations. Refer to the instructions of the electrodes and the cable for the specific maintenance.
For assistance, refer to Gamma Cardio Soft Srl, Rome, Italy, www.GammaCardioSoft.it

The cleaning of the patient cables must only be carried out with the product disconnected. The use of a cloth moistened with suitable detergent solutions (non-ionic, surface-active) and disinfectant solutions (0.1-0.2% quaternary ammonia-based components) is recommended. After cleaning, use a cloth moistened with water in order to remove all detergent residues. Dry well the electrodes before use. Do not immerse the power cord and Gamma Cardio Soft acquisition unit in liquid solutions.

The electrodes can be washed with detergents and disinfectants suitable for surgical instruments. After cleaning, rinse with clean water and dry. Do not use ultrasonic baths for cleaning the electrodes.

The Gamma Cardio Soft acquisition unit can be cleaned with a cloth moistened with water and then dried with care.

Warning for environmental protection

In the European Union, this label indicates that this product must not be disposed of with household waste. The device should be disposed in an appropriate plant that is able to perform operations for recovery and recycling. Please protect the environment, deliver this device to a specialized centre at the end of life.

7.1 Warranty and Disclaimer

Gamma Cardio Soft guarantees that the product will be free from production defects, if and only if the product has been used according to the instructions for the twelve months following its first purchase. To this end, the date indicated on the original invoice or receipt will be considered.
Any use out of the specified intended use, and / or any bad or incorrect use of the product will make any warranty not applicable. Where applicable, failure to comply with any general and / or particular warning invalidate warranty automatically.
Gamma Cardio Soft Srl does not guarantee that the Gamma Cardio CG meets the needs and expectations of the purchaser and it does not assume any responsibility for any direct or indirect damage caused by the installation of software, improper use of the system or errors inherent in the program and / or in the system even in the case where the company had had prior knowledge that such damage could occur. The buyer is then responsible for the selection, installation of software and the use of the system and the results obtained.
All service must be performed only by authorized personnel of the Gamma Cardio Soft Srl and with original spare parts. Repairs carried out by unauthorized personnel and / or when spare parts are not original, this is a reason to make any warranty not applicable.
Gamma Cardio Soft Srl is not liable and cannot under any circumstances be held liable for errors and / or misuse of the product and the resulting accidents.
Within the limits established by Italian law, Gamma Soft Cardio Srl shall not under any circumstances and in any way be recognized responsible for any damage - whether direct, incidental, consequential, exemplary or punitive damages, for loss of business profits, business interruption of activity, loss of information or other pecuniary loss - due to the purchaser of the product or the subject on which it is used in operational use or inability to use the product. In any case, the responsibility of Gamma Cardio Soft Srl will be limited to an amount corresponding to the price actually paid for the Gamma Cardio CG.
Gamma Cardio Soft Srl expressly declares that the Gamma Cardio CG should be used only by qualified personnel in the use of electrocardiographic equipment. Gamma Cardio Soft Srl, moreover, expressly declares that only qualified personnel can perform ECG interpretation and the diagnosis of cardiac diseases.
Gamma Cardio Soft Srl warns buyers that interpretation of the ECG by unskilled personnel constitutes a serious potential danger to the health of patients. Always be informed and respect local medical regulation.

8 Technical Specifications

Gamma Cardio CG is a system for diagnostic electrocardiography able to record the standard 12-lead ECG one lead at a time. The following are the main performances.

8.1 Database

Feature	Performance
Ecg records and reports	Automatic storage of medical reports and ECG records
Electronic Health Record	Automatic storage of patient data, and fast retrieval of the associated ECG, and reports

8.2 Telemedicine functions

Feature	Performance
E-mail	Embedded integrated E-mail capability with fast delivery to address book recipients or telemedicine centres.
Fax	ECGs and reports can be transmitted via Printer or Fax. A PC including a modem card Fax and a fax printer is required
Assisted step-by-step interpretation capability	Tools for assisted rapid ECG interpretation (frequency rhythm, axis, assisted measuring, ...).
Assisted step-by-step fast recording capability	Step-by-step driven procedure for rapid ECG recording suitable for less experienced operators

8.3 Reporting

Feature	Performance
Report Format	Professional report module that can be saved in proprietary or standard Acrobat PDF format.
Print Preview	Print preview with zooming capability (X 2, X 3) and printing of ECG in high quality on plain paper A4 size.

8.4 ECG DIsplay

Feature	Performance
Filters in real time and in post-acquisition	Possibility of activating / deactivating filters in real-time mode or after the recording without degradation of the ECG
Filters	Baseline filters, Net filter, Muscle Noise filter at 25 and 35 Hz
Automatic recovery of isoelectric line	Automatic recovery of isoelectric line in the presence of high artefacts or defibrillator discharge. Manual recovery button is also available
Sensitivity and speed of the track in real time and in post-acquisition	Possibility of changing the parameters of sensitivity and speed in real-time or stored on the track with no degradation in quality
Recording Speed (zoom)	5, 10, 25, 50, mm /second + 75, 100, 200 mm /second (zoom recording speed)
Sensitivity (zoom)	5-10-20 mm/mv + 30, 40, 50 mm/mv (zoom recording sensitivity)
Pacemaker	Pacemaker display performance according to the standard AAMI EC 11
Scissor tool	The scissor tool allows the elimination of non-significant ECG segments.

8.5 Reporting tool

Feature	Performance
Ruler tool (calculating distances between two points of the ECG)	The ruler tool is used to calculate horizontal and vertical distances between two points on reporting the results in millimetres, milliseconds and millivolts beats per minute.
Automatic calculation of the frequency	The system automatically displays the distance in seconds between two QRS complexes and the instantaneous ventricular frequency (beats per second).
System for calculation of parameters of the ECG	(Extended Version)
Expert system query for reporting	System that identify set of conditions given the parameters of the ECG (Extended Version)

8.6 Electrical Specifications Acquisition Unit

Electrical Specifications	Performance
ECG Acquisition	In real time: in manual mode one channel at a time; in automatic acquisition of 12-lead ECG in sequence (single channel version).
Frequency input signal	0.05 to 150 Hz (AAMI EC 11)
Leads	Standard 12-lead ECG (AAMI EC 11)
Horizontal Resolution	0.83 milliseconds acquisition (1200 samples / second);
Vertical resolution (amplitude)	2.5 microvolt in acquisition
Dynamic Range	± 5 millivolts (AAMI EC11)
Accuracy: overall error	<± 5% (AAMI EC11)
Maximum potential bias on the electrodes	± 300 millivolts (AAMI EC11)
Time Constant	<3.2 sec. (AAMI EC11)
Input Impedance	> 20 M Ω (AAMI EC11)
CMRR	> 100 dB
Leakage current in the patient	Much lower than maximum limit (10 μ A)
Patient Input	Type CF (isolated) with protection against defibrillator discharge
Calibration	Calibration function with step 1 millivolt

8.7 Additional Features

Feature	Performance
Test	Built-in test that allows detecting faults in the acquisition unit at module level
Included Accessories	• terminals standard 12 lead patient cable • Electrodes: four clip electrodes and six precordial electrodes with suction cups • cable to connect PC to Acquisition Unit (USB 2.0 - A Male to B Male Cable) • user manual • CD with the ECG Application program
Weight	170 grams (without the patient cable and the USB)
Dimensions	9 × 15 × 2 cm (Acquisition unit)
Supply	Power from the USB port (no need for batteries or transformers connected to the mains).
Connection to the PC	USB port
Environmental conditions	Operating: 5 ° C to 40 ° C, humidity 25% to 95%;

	Storage: -20 C to 65 ° C, humidity 10% to 95%;
Safety Rules	Medical device class IIB, IEC / EN 60601, IEC / EN 60601-1. IEC / EN 60601-2-25
Electromagnetic compatibility	IEC / EN 60601-1-2
Safety class	Class I (IEC / EN 601-1) Class IIb (93/42/EEC standards).

The technical characteristics and the figures shown in this publication are subject to change for updates in the used technology in software or in changed requirements.

8.8 Versions

The Gamma Cardio CG is sold in the following versions:

Version	Special features
Base	
Patient	Specific version for trained patients
Extended	Contains additional features (see previous paragraphs)
Multichannel	Allows the simultaneous acquisition of all channels

Table 5: Versions of Gamma Cardio CG

The acquisition unit can be connected to the PC through the USB port or serial port.

8.9 Electro Magnetic Compatibility Tables

The following table shows the EMC emission and immunity performances according to Article 6 of EN 60601-1-2. Such performances are based on evidences and tests.

Aspects of emission		
Emission test	**Compliance**	**Electromagnetic environment – guide**
RF emissions CISPR 11	Group 1	Equipment in which there is **intentionally generated** or used **conductively coupled** RF energy that is necessary for the internal functioning of the equipment itself Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	Equipment suitable for **use in all domestic establishments** and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes

Aspects of immunity			
The product is intended for use in the electromagnetic environment specified below. The customer or the user should ensure that the product is used in the specified environment			
Immunity Test	**Test level IEC/EN 60601-1-2**	**Level of Compliance**	**Electromagnetic environment guide**
Electrostatic discharge IEC/EN 61000-4-2	± 6 kV in contact ± 8 kV in air	± 6 kV in contact ± 8 kV in air	Floors should be wood, concrete or ceramic tile; if floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC/EN 61000-4-4	± 1 kV signal lines	± 2 kV lines signal supply	The quality of the mains voltage should be that of a typical commercial or hospital environment.

Magnetic field IEC/EN 61000-4-8	3 A/m	3 A/m	Magnetic fields at mains frequency should be at values of a typical area in a commercial or hospital environment.

Aspects of immunity to RF			
The ECG product is intended for use in the electromagnetic environment specified below. The customer or the user should ensure that the device is used in such an environment.			
Immunity test	**Test level to EN 60601-1-2**	**Level of compliance**	**Electromagnetic environment – guide**
RF conducted EN 61000-4-6	3 V_{rms} from 150 kHz to 80 MHz	3 V_{rms} from 150 kHz to 80 MHz	The RF communications equipment (portable and mobile) should not be used near to any part of the ECG, including cables, except for equipment that complies with the recommended separation distances calculated according to the equation applicable for the transmitter frequency. Recommended separation distances $d = 1.2 \cdot \sqrt{P}$ from 150 kHz to 80 MHz $d = 1.2 \cdot \sqrt{P}$ from 80 MHz to 800 MHz $d = 2.3 \cdot \sqrt{P}$ from 800 MHz to 2.5 GHz where P is the maximum rated output power of the transmitter in watts (W) according to the transmitter manufacturer and d is the separation distance in meters (m).
RF Radiated EN 61000-4-3	3 V_{rms} from 80 MHz to 2.5 GHz	3 V_{rms} from 80 MHz to 2.5 GHz	
The field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, may be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with this symbol:			

Recommended separation distance between portable and mobile radio communication equipment and the ECG device			
The ECG product is intended for use in an electromagnetic environment in which the radiated RF interference is under control. The customer or the operator of the device can help prevent electromagnetic interference by maintaining a minimum distance between RF mobile and portable communication devices (transmitters) and the ECG device, as recommended below, based on the maximum output power of the radio equipment.			
Maximum rated power output of the transmitter (W)	**Separation distance to the transmitter frequency (m)**		
	150 kHz to 80 MHz **$d = 1.2 \cdot \sqrt{P}$**	**From 80 MHz to 800 MHz** **$d = 1.2 \cdot \sqrt{P}$**	**800 MHz to 2 GHz** **$d = 2.3 \cdot \sqrt{P}$**
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not included above, the recommended separation distance d in meters (m) can be calculated using the equation applicable to the frequency of the transmitter, where P is the maximum rated output of the transmitter in watts (W) according to the transmitter manufacturer. Notes: 1. At 80 MHz and 800 MHz, the applicable frequency range is the highest 2. These guidelines may not be applicable in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

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